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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,417	01/04/2002	Ramesh Kekuda	21402-235 (CURA-535)	7162

7590 03/24/2004
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Boston, MA 02111

EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,417

Applicant(s)

KEKUDA ET AL

Examiner

James Martinell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8, 10, 12-14, 19-21, 39, 42, 46, 47 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-55 is/are allowed.
- 6) ☐ Claim(s) 5-8, 10, 12-14, 19-21, 39, 42, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/30/02, 11/21/03, 11/22/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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No copy of Sottrup-Jensen et al (Proc. Natl. Acad. Sci. USA 81 (23), 7353 (1984) is in the file, so this reference has not been considered by the examiner. The other references crossed out from the Information Disclosure Statement forms submitted by applicants are duplicate entries.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlink and/or other form of browser-executable code appear in at least the following locations:

- (a) page 14, line 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "naturally-occurring allelic nucleic acid variant" (claim 6) is vague, indefinite, and incomplete because the term "naturally-occurring" is a relative one that uses a frame of reference that is not known. One cannot know whether a sequence is non-naturally-occurring by having the sequence itself because this is not a property of the sequence. Thus, the metes and bounds of the claims are not clear.
- (b) The recitation of "naturally-occurring polypeptide variant" (claim 7) is vague, indefinite, and incomplete because the term "naturally-occurring" is a relative one that uses a frame of reference that is not known. One cannot know whether a sequence is non-naturally-occurring by having the sequence itself because this is not a property of the sequence. Thus, the metes and bounds of the claims are not clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8, 10, 12-14, 19-21, 39, 42, 46, and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of defined sequence, does not reasonably provide enablement for nucleic acids of recited percentage sequence identities or nucleic acids that encode polypeptides of recited percentage sequence identities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant application does not provide adequate guidance for one of skill in the art to arrive at a reasonable number of nucleic acid sequences that encode active variants of SEQ ID NO: 46. For example, there are no fewer than 6.5×10^{50} possible insertion variants of SEQ ID NO: 46 that vary by no more than 5% in sequence identity from SEQ ID NO: 46. Without guidance as to which variants may be active, one of skill in the art would be compelled to perform undue experimentation to practice the claimed invention.

Claims 39 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant application does not teach a pharmaceutical use for any of the nucleic acids mentioned in the claims.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Adams et al (Nature 377 (6547 Suppl), 3 (1995)). SEQ ID NO: 45 shares a run of 67 nucleotides with the sequence of Adams et al (see the alignment in Appendix A attached to this Office action). Since maximal stability of a double helix in a renaturation reaction is reached at 25-50 base pairs as taught in Kennell, Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971) in the paragraph bridging pages 260-261, it is clear that the DNA of Adams et al would hybridize under stringent conditions to SEQ ID NO: 45. Thus, the DNA of Adams et al is embraced by the claim.

Claims 50-55 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631 3/20/04